

DPP Data Archive

The full scale DPP data release Archive contains: (1) descriptive documentation; (2) study forms; and (3) the full scale DPP data release.

The files in the Archive are organized into the following three directories:

1. Documentation
2. Forms
3. Data

1. Documentation Directory

The Documentation directory contains the subdirectory *DPP_2008_Data_Release_Docs*, as well as several documents detailing the DPP study. In addition to the documentation included in the archive, the Manual of Operations is available for approved projects¹.

Also, for a list of study publications, see <http://www.bsc.gwu.edu/dpp/pps/registry.cgi>.

The *Documentation* directory contains documentation from the study and descriptive documentation developed by and stored in the NIDDK Data Repository. It includes the following documents:

- DPP Protocol (DPP Protocol.pdf). 119 pages.
- DPP General Description – Description of the clinical trial, de-identification, definition of diabetes, descriptions of variables, and data dictionaries for data releases. (DPP_Study_Website_General_Description_v2.0.pdf).
- DPP Metadata. (DPP_Study_Website_Metadata_v2.0.pdf).
- Study Timetable – Phase I, July 1994 through Study End June 2003. (Study_Timetable.pdf).

The *DPP_2008_Data_Release_Docs* subdirectory contains the following documents:

- DPP Data Release Documentation; February 2008 Full Scale Data Release – Description of the data contained in the full scale release. (DPP_Data_Release_Documentation_Full_Scale_2008.pdf). 26 pages.
- DPP Dataset Integrity Check Reports – Reports of five examinations of the data conducted by statisticians and quality control specialists at the Repository to provide confidence that the data archive distributed by the Repository is a true copy of the study data. (DSIC_DC2000_v1.0.pdf, DSIC_DC2005_V1.0.pdf, DSIC_Diab2005_trog_v1.0.pdf, DSIC_Diabetes2005_v1.0.pdf, and DSIC_NEJM2002_v1.0.pdf).

¹ The DPP DCC requested that the MOOP and Q-forms be released only to approved projects. Although access to these documents can be requested, they are not currently included in the archive at this time, pending NIDDK's resolution of the copyright issues.

2. Forms Directory

The Forms directory contains the forms used for data collection. All of the paper forms listed below are in Adobe PDF format. The forms and variables are described in Section 4 of the “Diabetes Prevention Program Data Release Documentation; February 2008 Full Scale Data Release”

[Documentation\DPP_2008_Data_Release_Docs\DPP_Data_Release_Documentation_Full_Scale_2008.pdf]. A listing of the forms and associated datasets is provided in Appendix A. In addition to the forms included in the archive, a full set of Questionnaires (Q-forms) is available for approved projects¹. Several of the Q-forms that are not copyrighted are included in the archive.

Screening Forms

- Form S01 Eligibility Checklist (S01.pdf) – Inclusion and exclusion criteria for potential participants. 6 pages.
- Form S03 Screening Step 2 Inventory (S03.pdf) – BMI, BP, urinalysis, current medications, pregnancy, diabetes, OGTT qualification, OGTT progression, OGTT local results, demographics, and complete blood count (CBC) results. 9 pages.
- Form S05 Screening Step 3 Inventory - Start (S05.pdf) – Family history, weight, smoking, aspirin use, cardiovascular and stroke/TIA, other diseases/symptoms, diet, medical history for women, biometrics, BP, dispensing of medication for run-in. 16 pages.
- Form S06 Screening Step 3 Inventory - End (S06.pdf) – Run-in compliance, adverse event assessment, personal and socioeconomic information. 3 pages.
- Form S07 Screening Step 4 Inventory - Randomization (S07.pdf) – Adverse events, pregnancy, prescription medications, final eligibility review, randomization, dispensing of coded medication. 3 pages.

Follow-up Forms (Post-Randomization)

- Form F01 Standard Follow-up Visit Inventory (F01.pdf) – Completed every 3 months between annual follow-up visits. Weight, BP, adverse events, pregnancy, concomitant prescriptions, medication compliance and dispensing, and CBC results. 5 pages.
- Form F02 Major Follow-up Visit Inventory (F02.pdf) – Completed during annual follow-up visits (end-year 1, end-year 2, etc.), end of study and at the time of the primary outcome (confirmed development of diabetes): biometrics, BP, adverse events, pregnancy, concomitant prescriptions, medication compliance and dispensing, and CBC results. 6 pages.
- Form F03 Interim Follow-up Visit Inventory (F03.pdf) – Completed at titration visits for coded metformin and follow-up visits when Form F01 and Form F02 are not completed. Reason for visit, adverse events, pregnancy questions, coded medication and BP for hypertension management. 3 pages.
- Form F04 Missed Follow-up Visit Report (F04.pdf) – Missed standard or major scheduled follow-up visit. Date and reason for the missed visit. 1 page.

- Form F05 Medication Adherence Interview (F05.pdf) – Completed when medication adherence is assessed on Form F01 or Form F02, also Form F03 for Month 1. Only for subjects who had taken coded metformin since the previous visit. Data from F05 were transferred to Section H (Coded Medication) of the corresponding Follow-up Visit Inventory. Medication adherence questions. 2 pages.
- Code Sheet for the Medication Adherence Interview (F05_Med_Adhere_Codes.pdf) – Reasons for noncompliance, strategies for improved compliance. 2 pages.
- Form F06 Home Visit Inventory (F06.pdf) – Inactive participants off their coded medication for any Mid-Year or Annual visit conducted outside the DPP clinic. Adverse events, prescription medications. 2 pages.

Lifestyle Intervention Group Forms

- Form L03 - Lifestyle Contact - In Person (L03.pdf) – Completed for all in-person contacts: Includes nature of session (type and duration), self-monitoring information, physical activity, and weight status. 5 pages.
- Form L04 - Lifestyle Physical Activity Log (L04.pdf) – Completed for each supervised physical activity session. Type of activity, list of attendees. 1 page.
- Form L05 - Lifestyle Group Session Log (L05.pdf) – Completed for each group session. Type of activity, list of attendees. 1 page.
- Lifestyle intervention codes (L03_L04_L05_Lifestyle_Codes.pdf). Exercise and lifestyle codes. 13 pages.

Event Data forms

- Form E01 Adverse Event Report (E01.pdf) – New symptoms, injuries, illness, side effects, or worsening of pre-existing conditions. Adverse event classification and possible interventions (metformin, diet, exercise). 4 pages.
- Form E02 Serious Adverse Event Report (E02.pdf) – Hospitalization, cancer, disability, death, use of metformin, treatment, use of insulin, outcome. 4 pages.
- Form E04 Pregnancy Confirmation Report (E04.pdf) – For subjects who had a positive pregnancy test. Metformin discontinued. 2 pages.
- Form E05 Pregnancy Outcome Report (E05.pdf) – For subjects whose pregnancy had ended. 2 pages.
- Form E06 Mortality Event Report (E06.pdf) – Circumstances of death, use of metformin, causes of death. 3 pages.

Heart Disease Risk Form

- Form R04 CHD Risk Status Report (R04.pdf) – Coronary heart disease risk, risk factors, need to unmask lipid profile. 2 pages.

Troglitazone Forms

- Form TR1 Participants Randomized to Troglitazone Follow-Up Visit Inventory (TR1.pdf) – Mid-year and annual follow-up visits for participants randomized to troglitazone. (End-month 6, 12, 18, etc.). Weight, BP, adverse events and concomitant medications. 3 pages.
- Form TR02 Participants Randomized to Troglitazone Group Session Log (TR2.pdf) – Completed for each troglitazone group session. Type of activity, list of attendees. 1 page.

Questionnaire Forms

- Form Q05 NHANES III Physical Activity Scale (Q01.pdf) – Interviewer-administered at the Step 3-Start visit only, and was used to compare the DPP participants to the national sample of NHANES participants. Amount and types of physical activity in the past month. 4 pages.
- Form Q06 Retention and Treatment Monitoring Measures (Q06.pdf) – Self-administered at the Step 3-End visit and at mid-year visits throughout DPP. Life events, social provisions scale, and family assessment. 8 pages.
- Form Q08 Interval History Questionnaire (Q08.pdf) – Completed by study staff at all annual visits after baseline. Updated medical information, such as cardiovascular history, as well as drinking, smoking, aspirin, and routine medical care. 6 pages.
- Form Q09 DPP-Specific Support Measure – Baseline Visit (Q09.pdf) – Self-administered prior to randomization at the Step 3-End visit. Participants' anticipated social support of their DPP participation. 2 pages.
- Form Q10 DPP-Specific Support Measure – Follow-Up Visits (Q10.pdf) – Self-administered at each annual visit after randomization. Participants' observed social support of their DPP participation. 3 pages.
- Form Q12 Economic Evaluation Questionnaire (Q12.pdf) – Self-administered one time by each participant during mid- to late- 2000. Participants' cost and time related to food purchase and preparation, exercise behavior and equipment, and medical care during DPP participation. 5 pages.
- Form Q13 Urinary Incontinence Questionnaire (Q13.pdf) – Self-administered one time by each participant during mid-2001. Participants' issues related to urinary incontinence in the past year. 3 pages.

3. Data Directory

The Data directory contains the subdirectory *DPP_Data_2008*.

The *DPP_Data_2008* subdirectory contains the full-scale data. The data are contained in the following two subdirectories:

- Form Data:** Data collected on forms, as specified in section 4.4-4.10 of “Diabetes Prevention Program Data Release Documentation February 2008 Full Scale Data Release”
 [Documentation\DPP_2008_Data_Release_Docs\DPP_Data_Release_Documentation_Full_Scale_2008.pdf]. Contains a **Data** folder and a **Data Dictionary** folder. The **Data** folder contains the .sas7bdat files listed below. There is a .sas7bdat file for each of the 30 Forms; it contains the data collected using that form. The **Data Dictionary** folder contains the .doc files listed below. There is a .doc file for each form; it describes the variables in the form. Instructions for opening the .sas7bdat file can be found on page 5 of the “Diabetes Prevention Program Data Release Documentation February 2008 Full Scale Data Release” document.

Data	Data Dictionary
E04.sas7bdat	E04.DOC
E05.sas7bdat	E05.DOC
F01.sas7bdat	F01.DOC
F02.sas7bdat	F02.DOC
F03.sas7bdat	F03.DOC
F04.sas7bdat	F04.DOC
F05.sas7bdat	F05.DOC
F06.sas7bdat	F06.DOC
L03.sas7bdat	L03.DOC
L04.sas7bdat	L04.DOC
L05.sas7bdat	L05.DOC
Q01.sas7bdat	Q01.DOC
Q02.sas7bdat	Q02.DOC
Q03.sas7bdat	Q03.DOC
Q04.sas7bdat	Q04.DOC
Q05.sas7bdat	Q05.DOC
Q06.sas7bdat	Q06.DOC
Q08.sas7bdat	Q08.DOC
Q09.sas7bdat	Q09.DOC
Q10.sas7bdat	Q10.DOC
Q12.sas7bdat	Q12.DOC
Q13.sas7bdat	Q13.DOC
R04.sas7bdat	R04.DOC
S01.sas7bdat	S01.DOC
S03.sas7bdat	S03.DOC
S05.sas7bdat	S05.DOC
S06.sas7bdat	S06.DOC
S07.sas7bdat	S07.DOC
TR1.sas7bdat	TR1.DOC
TR2.sas7bdat	TR2.DOC

- **Non-Form Data:** Data not collected on forms but for which datasets are included in this release, as specified in section 4.11 – 4.12 of “Diabetes Prevention Program Data Release Documentation February 2008 Full Scale Data Release” [Documentation\DPP_2008_Data_Release_Docs\DPP_Data_Release_Documentation_Full_Scale_2008.pdf]. Contains a **Data** folder and a **Data Dictionary** folder. The **Data** folder contains the .sas7bdat files listed below. The **Data Dictionary** folder contains the .doc files listed below. There is a .doc file for each dataset; it describes the dataset variables.

For additional information on the structure and contents of these datasets and statistical considerations of the analysis, see the “Diabetes Prevention Program Data Release

Documentation February 2008 Full Scale Data Release” document. Also, instructions for opening the .sas7bdat files can be found on page 5 of this document.

Data	Data Dictionary
BASEDATA.sas7bdat	BASEDATA.DOC
CT.sas7bdat	CT.DOC
EVENTS.sas7bdat	EVENTS.DOC
LAB.sas7bdat	LAB.DOC
NCC.sas7bdat	NCC.DOC
QWB.sas7bdat	QWB.DOC

Appendix A: Listing of DPP Forms and Datasets

Form Name	Data File Name	Variables	Size
E01 Adverse Event Report	---	---	---
E02 Serious Adverse Event Report	---	---	---
E04 Pregnancy Confirmation	E04.sas7bdat	11	6 KB
E05 Pregnancy Outcome	E05.sas7bdat	21	6 KB
E06 Mortality Event	---	---	---
F01 Standard Follow-up Visit Inventory	F01.sas7bdat	43	4.86 MB
F02 Major Follow-up Visit Inventory	F02.sas7bdat	72	2.13 B
F03 Interim Follow-up Visit Inventory	F03.sas7bdat	32	1.4 MB
F04 Missed Follow-up Visit Report	F04.sas7bdat	9	111 KB
F05 Medication Adherence Interview	F05.sas7bdat	19	2.35 MB
F06 Home Visit Inventory	F06.sas7bdat	17	3.0 KB
L03 Lifestyle Contact - In Person	L03.sas7bdat	62	10.9 MB
L04 Lifestyle Physical Activity Log	L04.sas7bdat	33	924 KB
L05 Lifestyle Group Session Log	L05.sas7bdat	33	193 KB
Form Q01 Beck Questionnaires	Q01.sas7bdat	50	1.12 MB
Form Q02 Health Survey Questionnaire	Q02.sas7bdat	42	1.65 MB
Form Q03 Modifiable Activity Questionnaire	Q03.sas7bdat	222	6.53 MB
Form Q04 Low Level Physical Activity Recall	Q04.sas7bdat	50	3.04 MB
Form Q05 NHANES III Physical Activity Scale	Q05.sas7bdat	47	523 KB
Form Q06 Retention And Treatment Monitoring Measures	Q06.sas7bdat	71	2.64 MB
Form Q08 Interval History Questionnaire	Q08.sas7bdat	61	1.70 MB
Form Q09 DPP-Specific Support Measure - Baseline Visit	Q09.sas7bdat	7	224 KB
Form Q10 DPP-Specific Support Measure - Follow-up Visits	Q10.sas7bdat	12	614 KB
Form Q12 Economic Evaluation Questionnaire	Q12.sas7bdat	51	441 KB
Form Q13 Urinary Incontinence Questionnaire	Q13.sas7bdat	16	249 KB
Form R04 CHD Risk Status Report	R04.sas7bdat	15	1.37 MB
Form S01 Eligibility Checklist	S01.sas7bdat	34	723 KB
Form S03 Screening Step 2 Inventory	S03.sas7bdat	56	754 KB
Form S05 Screening Step 3 Inventory - Start	S05.sas7bdat	173	1.58 MB
Form S06 Screening Step 3 Inventory - End	S06.sas7bdat	23	324 KB
Form S07 - Screening Step 4 Inventory - Randomization	S07.sas7bdat	28	401 KB
Does Not Apply	TR1.sas7bdat	25	383 KB
Does Not Apply	TR2.sas7bdat	33	27 KB
Does Not Apply	BASEDATA.sas7bdat	6	269 KB
Does Not Apply	CT.sas7bdat	7	164 KB
Does Not Apply	EVENTS.sas7bdat	11	332 KB
Does Not Apply	LAB.sas7bdat	33	5.14 MB
Does Not Apply	NCC.sas7bdat	150	6.80 MB
Does Not Apply	QWB.sas7bdat	9	553 KB